

Atty Dkt. No.: BEAR006  
USSN: 09/641,034

## II. REMARKS

### Formal Matters

Claims 1-16 are pending after entry of the amendments set forth herein.

Claims 1-5, 7-9, and 12-16 were examined and were rejected. Claims 6, 10, and 11 were withdrawn from consideration.

Claims 1, 8, and 16 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim. Support for the amendments to claims 1, 4, 8, and 16 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: paragraphs 0051 and 0052 of the Substitute Specification. Accordingly, no new matter is added by these amendments.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

### Examiner Interview

The undersigned Applicants' representative wishes to thank Examiner Mayes for the courtesy of an in-person interview which took place on June 25, 2003 and which was attended by Applicants' representative Paula A. Borden, Examiner Mayes, and Yoshi Kumagai, who participated by telephone. During the interview, claim amendments and the cited art were discussed.

### Rejection under 35 U.S.C. § 102(a)

Claims 1-5, 7-9, 12, and 16 were rejected under 35 U.S.C. § 102(a) as allegedly anticipated by WO 99/60017

The Office Action stated that WO 99/60017 teaches a protein (SEQ ID NO:2) comprising an amino acid sequence identical to SEQ ID NO:47) which is comprised of about 10 to about 50 amino acids, and RGD sequence, and biological activity that enhances bone growth. Applicants respectfully traverse the rejection.

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Claim 1, 8, and 16 as amended recite a peptide consisting of from 10 to 50 amino acids. The peptides as claimed comprise an integrin binding motif, as recited in claim 1, or an RGD motif, as recited in claims 8 and 16. The peptides as claimed enhance or promote bone growth.

WO 99/60017 neither discloses nor suggests a peptide of from 10 to 50 amino acids in length that comprises an integrin binding motif or an RGD sequence, and that enhances or promotes bone growth. Accordingly, WO 99/60017 cannot anticipate claims 1-5, 7-9, 12, and 16.

WO 99/60017 relates to matrix extracellular phosphoglycoprotein (or "phosphatonin"). WO 99/60017 states that phosphatonin polypeptides can be used to treat disease, e.g., to improve impaired bone formation, and states that an MEPE motif is a pre-requisite for normal bone mineralization and growth. WO 99/60017, page 49, lines 8-26. The MEPE motif is in the C-terminus of phosphatonin. WO 99/60017, page 49, lines 22-26. There is no disclosure or suggestion in WO 99/60017 of any peptide of 10-50 amino acids in length and comprising an integrin binding motif, e.g., an RGD motif, which peptide is effective in enhancing or promoting bone repair. Accordingly, WO 99/60017 cannot anticipate the instant invention as claimed.

During the Examiner Interview, Examiner Mayes suggested amending the claims to recite a peptide "consisting of from about 10 to about 50 amino acids." Such claim language has been incorporated into claims 1, 8, and 16.

Applicants submit that the rejection of claims 1-5, 7-9, 12, and 16 under 35 U.S.C. §102(a) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C. §103(a)

Claims 1-5, 7-9, and 12-16 were rejected under 35 U.S.C. §103 as allegedly unpatentable over U.S. Patent No. 5,015,628 ("Reynolds") in view of WO 99/60017 and U.S. Patent No. 5,837,674 ("Kumagai").

The Office Action stated that: 1) Reynolds teaches the use of phosphopeptides that are biologically active in promoting bone growth, and may be used to treat the teeth by administering a mouthwash or toothpaste comprising phosphopeptides; 2) WO 99/60017 teaches a peptide comprise of

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ten to 50 amino acids, and RGD sequence, amino acids substantially the same as those contiguous with an RGD sequence of naturally occurring matrix extracellular phosphoglycoprotein, and which is biologically active in promoting bone growth; 3) WO 99/60017 does not teach such a formulation is a toothpaste or mouthwash or the carrier is saline; 4) Kumagai teaches the use of phosphopeptides that are biologically active in promoting bone growth, and may be administered by saline formulation that is injectable.

The Office Action concluded that it would be obvious to administer the phosphopeptide as claimed in the present invention as a mouthwash, toothpaste, or in saline to treat and maintain the teeth and bones in mammals. Applicants respectfully traverse the rejection.

Reynolds neither teaches nor suggests the instant invention as claimed. Reynolds does not teach peptides that are "similar to those in the present invention," as asserted in the Office Action. Office Action, page 5. Instead, Reynolds relates to **phosphopeptides** and uses of same.

Kumagai cannot cure the deficiency of Reynolds. Kumagai relates to **phosphopeptides** and uses of same.

WO 99/60017 cannot cure the deficiency of Reynolds. As discussed above, WO 99/60017 neither discloses nor suggests a peptide of 10-50 amino acids in length and comprising an integrin binding motif, e.g., an RGD motif, which peptide is effective in enhancing or promoting bone repair. Accordingly, Reynolds, alone or in combination with WO 99/60017 and/or Kumagai, cannot render claims 1-5, 7-9, and 12-16 obvious.

Applicants submit that the rejection of claims 1-5, 7-9, and 12-16 under 35 U.S.C. §103(a) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

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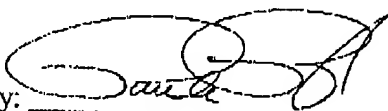
### III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number BEAR006.

Respectfully submitted,  
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